DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

g1653d

WARNING LETTER
VIA EXPRESS MAIL

AUG 21 2001

Mr. Thomas Brown
President
SPLINTEK-PP, INC.
3325 Wyoming Street
Kansas City, Missouri 64111

Dear Mr. Brown:

This letter is in response to the August 8, 2001, letter from Mr. Alan Schwartz, Executive VP, MDI Consulants, Inc., in which he replied on Splintek's behalf that the EZ-Splint and EZ-Splint PM are "being marketed and are substantial to the [redacted] and the [redacted]."

The Center for Devices and Radiological Health (CDRH) has determined that this response is not adequate. The Office of Device Evaluation (ODE) has determined that the EZ-Splint and EZ-Splint PM are unclassified devices that have the product code MQC, diagnostic nightguard appliance. This determination is made based on the medical claims in the EZ-Splint's and EZ-Splint PM's labeling, advertising, and/or accompanying literature.

This letter is to inform you that under section 510(k) of the Federal, Food, Drug and Cosmetic Act, you are required to notify the Food and Drug Administration (FDA) at least ninety (90) days prior to introduction of a device into commercial distribution in the United States. This requirement is accomplished by the submission of a Premarket Notification (510(k)). This helps protect the public health by ensuring that medical devices are shown to be both safe and effective or substantially equivalent to other devices already legally marketed in this country. The information necessary to comply with the 510(k) requirement is found in Title 21 Code of Federal Regulations (21 CFR), Part 807, Subpart E – Premarket Notification Procedures. You can also obtain additional information through use of the Internet website, http://www.fda.gov.

Our records show that you did not obtain market clearance before you began offering the EZ-Splint and EZ-Splint PM for sale. Because you do not have marketing clearance from FDA, marketing your products are in violation of the law. In legal terms, the aforementioned devices are adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your products are adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your devices are safe and effective. Your products are misbranded under the Act because you did not submit information that shows your devices are substantially equivalent to other devices that are legally marketed.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please notify this office in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to:

Mr. Ronald L. Swann
Food and Drug Administration
Dental, ENT & Ophthalmic Devices Branch
2094 Gaither Road, HFZ-331
Rockville, MD 20850

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at 1(800) 638-2041.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Ernest N. Smith at (301) 594-4613.

Sincerely yours,

Larry Spears
Acting Director
Office of Compliance
Center for Devices and Radiological Health

Enclosure